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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,847	02/10/2006	Tatsuo Hoshino	21416 US C038435/0185663	2023

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,847	HOSHINO ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *12-26 and 36-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/EP03/10683.

The preliminary amendment filed on 3/23/2005 amending claims 3-8, 10, and adding new claims 27-49 is acknowledged. Claims 1-49 are pending.

Applicant's election of Group I, Claim 1-11 and 27-35, in the communication filed on 6/19/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12-26 and 36-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim 1-11 and 27-35 are under consideration and are being examined herein.

Priority

Acknowledgement is made of applicants claim for foreign priority of EP 02021625.5 of 9/27/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/23/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawing of this application submitted on 3/23/2005is being considered by the examiner.

Claim Objections

Claims 3 and 27 are objected to because of the following informalities: "amino acid sequence which is identified by SEQ ID NO: 3" should be "the amino acid sequence of SEQ ID NO: 3". Appropriate correction is required.

Claim 1, part (d) is objected to because of the following informalities: "by way of substitution" should be "by substitution". Appropriate correction is required.

Claim 1 is objected to because of the following informalities: "comprising a nucleic acid molecule one or more selected" should be "comprising a nucleic acid molecule selected". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10 and 34 recite a "recombinant organism" which encompasses a transformed human. Human beings are non-statutory subject matter. **MPEP 2105** states that if the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then the claimed invention is directed to nonstatutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 28 recite "said polynucleotide is derived from a strain', which is unclear if the term "derived" includes only the wild type sequence or includes mutants, variants or fragments thereof, which are unknown, thereby rendering the scope of the claim(s) indefinite. The recitation "derived" can be replaced with "isolated".

Claims 1-11 and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claims 1 and 2 recite "under stringent conditions", but the specification does not define what conditions constitute "stringent". While page 5 and 6 attempt to describe a stringent condition, the description is merely exemplary and not a clear definition. In the art the meaning of the term "stringent" varies widely depending on the individual situation and the person making the determination. Accordingly, claims 3-11 and 27-35 are rejected, as they are dependent on claims 1 and 2.

Claims 1-11 and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claims 1 and 2 recite "complementary strand" which is unclear as to whether it is limited to the complete complementary strand or includes fragments thereof. Accordingly, claims 3-11 and 27-35 are

rejected, as they are dependent on claims 1 and 2. For purpose of the further examination, it is presumed that applicants intended the complete complementary strand.

Claims 9 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claims 9 and 33 recite "baculovirus" as a host organism. Baculovirus is virus or a viral vector, not a host organism (the host used with baculovirus vectors is usually insect cells).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 2 directed to any DNA molecule encoding any polypeptide having acetyl-CoA carboxylase (ACC) activity or any DNA molecule encoding any polypeptide having one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3 or any DNA molecule encoding polypeptide having 56.3% sequence identity to SEQ ID NO: 3 or any DNA molecule encoding any polypeptide having any fragment of SEQ ID NO: 3 or any DNA molecule comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1 or any DNA molecule which hybridize with the complement of SEQ ID NO: 2 or SEQ ID NO: 1

under stringent conditions. Claim 3 recites the DNA molecule, wherein said DNA molecule encodes amino acid sequence of SEQ ID NO: 3 or has identity of 56.3 % or more with SEQ ID NO: 3 and claim 4 recites the DNA molecule, wherein said DNA molecule is derived from a strain of P. rhodozyma or Xanthophyllomyces dendrorhous. Claim 5 recites a method for making a recombinant vector comprising inserting said polynucleotide into a vector and claim 6 recites a recombinant vector containing the said polynucleotide. Claim 7 recites the vector having said polynucleotide is operatively linked to expression control sequences allowing expression in prokaryotic or eukaryotic cells and claim 8 recites a method of making a recombinant organism comprising introducing the vector comprising said DNA molecule into a host organism. Claim 9 recites the method, wherein said host organism is selected from E. coli, baculovirus, or S. cerevisiae and claim 10 recites the recombinant organism containing the vector. Claim 11 recites a process for producing a polypeptide having acetyl-coA carboxylase activity comprising culturing the recombinant organism and recovering the polypeptide from the culture of said recombinant organism. Claim 27 recites the isolated polynucleotide, wherein said polynucleotide encodes amino acid sequence of SEQ ID NO: 3 or has identity of 56.3 % or more with SEQ ID NO: 3 and claim 28 recites the isolated polynucleotide, wherein said polynucleotide is derived from a strain of P. rhodozyma or Xanthophyllomyces dendrorhous. Claim 29 recites a method for making a recombinant vector comprising inserting the said polynucleotide into a vector and claim 30 recites a recombinant vector containing the said polynucleotide. Claim 31 recites the vector in which the said polynucleotide is operatively linked to expression control regulatory sequences allowing expression in prokaryotic or eukaryotic cells. Claim 32 recites a method of making a recombinant organism comprising introducing the said vector into a host organism and

claim 33 recites the method, wherein said host organism is selected from E. coli, baculovirus, or S. cerevisiae. Claim 34 recites the recombinant organism containing the said vector and claim 35 recites a process for producing a polypeptide having acetyl-coA carboxylase activity comprising culturing the recombinant organism and recovering the polypeptide from the culture of said recombinant organism. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches the structure of only a single representative species of such acetyl-CoA carboxylase gene encoding proteins.

Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding the polypeptide having acetyl-CoA carboxylase activity. Given this lack of description of representative species encompassed by the genus of DNAs used in the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-11 and 27-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an acetyl-CoA carboxylase (ACC) gene of SEQ ID NO: 2 encoding protein of SEQ ID NO: 3 from P. rhodozyma, does not reasonably provide enablement for any ACC having one or more amino acid deletions, substitutions or additions to SEQ ID NO: 2 or one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3 or any DNA molecule encoding polypeptide having 56.3% sequence identity to SEQ ID NO: 3 or any DNA molecule encoding any polypeptide having any fragment of SEQ ID NO: 3 or any DNA molecule comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1 or any DNA molecule which hybridize with the complement of SEQ ID NO: 2 or SEQ ID NO: 1 under stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 2 are so broad as to encompass any ACC having one or more amino acid deletions, substitutions or additions to SEQ ID NO: 2 or one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3 or any DNA molecule encoding polypeptide having 56.3% sequence identity to SEQ ID NO: 3 or any DNA molecule encoding any polypeptide having any fragment of SEQ ID NO: 3 or any DNA molecule comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1 or any DNA molecule which hybridize with the complement of SEQ ID NO: 2 or SEQ ID NO: 1 under stringent conditions. Claim 3 recites the DNA molecule, wherein said DNA molecule encodes amino acid sequence of SEQ ID NO: 3 or has identity of 56.3 % or more with SEQ ID NO: 3 and claim 4 recites the DNA molecule, wherein said DNA molecule is derived from a strain of P. rhodozyma

or Xanthophyllomyces dendrorhous. Claim 5 recites a method for making a recombinant vector comprising inserting said polynucleotide into a vector and claim 6 recites a recombinant vector containing the said polynucleotide. Claim 7 recites the vector having said polynucleotide is operatively linked to expression control sequences allowing expression in prokaryotic or eukaryotic cells and claim 8 recites a method of making a recombinant organism comprising introducing the vector comprising said DNA molecule into a host organism. Claim 9 recites the method, wherein said host organism is selected from E. coli, baculovirus, or S. cerevisiae and claim 10 recites the recombinant organism containing the vector. Claim 11 recites a process for producing a polypeptide having acetyl-coA carboxylase activity comprising culturing the recombinant organism and recovering the polypeptide from the culture of said recombinant organism. Claim 27 recites the isolated polynucleotide, wherein said polynucleotide encodes amino acid sequence of SEQ ID NO: 3 or has identity of 56.3 % or more with SEQ ID NO: 3 and claim 28 recites the isolated polynucleotide, wherein said polynucleotide is derived from a strain of P. rhodozyma or Xanthophyllomyces dendrorhous. Claim 29 recites a method for making a recombinant vector comprising inserting the said polynucleotide into a vector and claim 30 recites a recombinant vector containing the said polynucleotide. Claim 31 recites the vector in which the said polynucleotide is operatively linked to expression control regulatory sequences allowing expression in prokaryotic or eukaryotic cells. Claim 32 recites a method of making a recombinant organism comprising introducing the said vector into a host organism and claim 33 recites the method, wherein said host organism is selected from E. coli, baculovirus, or S. cerevisiae. Claim 34 recites the recombinant organism containing the said vector and claim 35 recites a process for producing a polypeptide having acetyl-coA carboxylase activity comprising

culturing the recombinant organism and recovering the polypeptide from the culture of said recombinant organism. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of ACC gene encoding protein broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one acetyl-CoA carboxylase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any ACC having one or more amino acid deletions, substitutions or additions to SEQ ID NO: 2 or one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3 or any DNA molecule encoding polypeptide having 56.3% sequence identity to SEQ ID NO: 3 or any DNA

molecule encoding any polypeptide having any fragment of SEQ ID NO: 3 or any DNA molecule comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1 or any DNA molecule which hybridizes with the complement of SEQ ID NO: 2 or SEQ ID NO: 1 under any stringent conditions because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting acetyl-CoA carboxylase activity; (B) the general tolerance of acetyl-CoA carboxylase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any acetyl-CoA carboxylase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any ACC having one or more amino acid deletions, substitutions or additions to SEQ ID NO: 2 or one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3 or any DNA molecule encoding polypeptide having 56.3% sequence identity to SEQ ID NO: 3 or any DNA molecule encoding any polypeptide having any fragment of SEQ ID NO: 3 or any DNA molecule comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1 or any DNA molecule which hybridizes with the complement of SEQ ID NO: 2 or SEQ ID NO: 1 under any stringent conditions. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any ACC having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art

is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 10 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated host cells transformed with the recited nucleic acids, does not reasonably provide enablement for any host organism within a multicellular animal, which have been transformed with the recited nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 10 and 34 are so broad as to encompass any host organism or any host transformed with specific nucleic acids, including cell in *in vitro* culture as well as cells within any multicellular organism. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of host cell or organism broadly encompassed by the claims. While methods for transforming cell *in vitro* are well known in the art, methods for successfully transforming cells within complex multicellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within one multicellular organism are unlikely to be applicable to transformation of other types of multicellular organisms as multicellular organisms vary widely. However, in this case the disclosure is limited to only host cell in vitro.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multicellular organism for the

production of polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, expression of genes in a particular host cell having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is suggested that applicants limit the claims to "An isolated host cell".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-11 and 29-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Schnell et al. (WO 1999/32635, publication 6/1/1999, see IDS) Schnell et al. disclose the sequence of a protein of 2233 amino acid residues, which is 54% identical to SEQ ID NO: 3 of the instant application. Schnell et al. also disclose that the protein is acetyl-CoA carboxylase and the gene is isolated from fungi. Schnell et al. further disclose the cloning, expression of said gene and obtained the said acetyl-CoA carboxylase protein from transformed host cell S. cerevisiae and purified by standard purification methods. Schnell et al. also disclose a fragment of the protein and the probe DNA would hybridize with SEQ ID NO: 3. Because of the recitation of "having one or more amino acid deletions, substitutions or additions to SEQ ID NO: 2 or one or more amino acid substitution, deletion and/or additions to the SEQ ID NO: 3" or

"polynucleotide comprising 15 nucleotides of the polynucleotide of SEQ ID NO: 2 or SEQ ID NO: 1" or "polynucleotide which hybridizes with the complement of SEQ ID NO: 2 or SEQ ID NO: 1 under stringent conditions" render claims very broad and in view of these recitation, a skill artisan would reasonably believe that the polynucleotide encoding the protein of Schnell et al. would hybridize under at least low stringency condition with SEQ ID NO: 1 and 2. Therefore, Schnell et al. anticipate claims 1-2, 5-11 and 29-35 of the instant application.

Conclusion

Status of the claims:

Claims 1-11 and 27-35 are pending.

Claims 1-11 and 27-35 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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